Cryptosporidium/Giardia and Nitrosamine Precursor Occurrence from two Waste Water Treatment Plants in the Sacramento-San Joaquin Delta

Quality Assurance Project Plan

California Department of Water Resources

Municipal Water Quality Investigations

Draft

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Comment [m1]: There needs to a section of Reports to Management (Deliverables). You have a sentence on page 8 that you could expand. Deliverables are probably the number one items/s of interest to management and contractors or (read: funding source).

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1. Background

1.1 Problem Statement

Municipal waste water is known to contain elevated concentrations of two genera of pathogenic protozoa, Cryptosporidium and Giardia. Conventional waste water treatment does not effectively inactivate Cryptosporidium oocysts which can be infectious to humans. Municipal waste water also contains nitrosamine precursors which can become carcinogenic nitrosamines during the water treatment process for drinking water. Thus treated waste water has important health implications to sources of drinking water that receive them. The Sacramento-San Joaquin Delta (Delta) serves as a source of drinking water for over 25 million Californians and also receives treated waste water from multiple facilities. The two largest dischargers of treated waste water to the Delta are the Sacramento Regional County Sanitation District (SRCSD) Waste Water Treatment Plant (WWTP) and the City of Stockton Department of Municipal Utilities (MUD) WWTP.

1.2 Objectives

This Project is ~~collaboration~~collaboration between the California Department of Water Resources (DWR) Municipal Water Quality Program's Investigations Unit (MWQI) and the Metropolitan Water District of Southern California (MWD) aimed at assessing the current respective contributions of Cryptosporidium, Giardia, and nitrosamine precursors to the Delta from the SRCSD and Stockton MUD WWTP discharges. The Project is organized into two separate studies; a pathogen study led by the California Department of Water Resources and a nitrosamine precursor study led by MWD. The individual studies will be referred to as **Pathogen Study** and **NDMA** (N-nitrosodimethylamine) **Study** throughout this document.

1.3 Interested Parties

This project does not have a regulatory focus; however data obtained from this study are public domain and may be used by the Central Valley Regional Board for watershed assessments. Agencies likely to review the data include the California Department of Public Health, California Urban Water ~~Association~~Agencies, and the Central Valley Regional Water Quality Control Board.

Comment [m2]: Will all the data be public domain from the time the results are received from the lab? Does MWD agree? They may not agree to release data before they publish the results

2. Project Organization

2.1 DWR Project Personnel

MWQI personnel will coordinate and conduct monitoring of the WWTP discharges and the receiving water bodies. Carol DiGiorgio, the Program Manager, will be responsible for oversight and final review of the Project process. Joe Christen, the Principal Investigator of the Pathogen Study, will be responsible for coordinating with the contracted labs and scheduling field runs for the Project, as well as data management, data review, and all documentation of the pathogen study. Steve San Julian is the Municipal Water Quality Program's Field Support Unit (Field Unit) Supervisor and is responsible for scheduling and assigning Field Operators to the project. Eric Haydt, the Field Lead, is responsible for obtaining necessary field equipment, equipment maintenance, ensuring that sample collection follows established protocols, preparing sampling equipment and containers, and coordinating with the DWR Bryte Laboratory. Murage Ngatia, the Quality Assurance Officer, is responsible for reviewing the Quality Assurance Project Plan. Sid Fong is the supervising chemist and Quality Assurance officer at Bryte Laboratory. Sid Fong also manages contracts with non-DWR laboratories. Table 2-1 lists the DWR Project personnel and their contact information.

Table 2-1 DWR Project personnel, roles, and contact information.

Name	Role	Phone	Email
Carol DiGiorgio	Project Manager	916 376-9711	caroldi@water.ca.gov
Steve San Julian	Field Supervisor	916 371-2284	sjulian@water.ca.gov
Joe Christen	Principal Investigator	916 376-9710	jchriste@water.ca.gov
Eric Haydt	Field Lead	916 375-6809	ehaydt@water.ca.gov
Murage Ngatia	QA Officer	916 376-9714	mngatia@water.ca.gov
Ken New	Field Operator	916 375-8052	knew@watar.ca.gov
Mark Bettencourt	Field Operator	916 371-3118	mbett@water.ca.gov
Arin Conner	Field Operator	916 371-3121	aconner@water.ca.gov
Sid Fong	Supervising Chemist	916 375-6008	sfong@water.ca.gov

2.2 Other Parties

There are several non-DWR groups associated with this Project. The roles of non-DWR personnel associated with the Project are explained in this section and the contact information for key personnel is given in Table 2-2.

Mike Sclimenti and Stuart Krasner of MWD are the Lead Investigators of the NDMA Study. Mike Sclimenti is the principal contact for scheduling sample collection and logistics for MWD samples.

Stockton MUD will provide access to their final effluent at their WWTP in Stockton. Laura Lazzelle of the City of Stockton is the chief contact for obtaining permission to access the WWTP facility.

Cryptosporidium and Giardia enumeration will be conducted by BioVir laboratories in Benicia, California. Dr. Richard Danielson of BioVIr has been the lead contact for BioVir for technical issues and assistance. Dorian Celio of BioVir is the main contact for scheduling sample drop-offs, obtaining lab results, and shipping logistics. Liz Barriga is an alternate contact for sample logistics.

American Water of Voorhees, New Jersey will be performing infectivity and genotype analyses on Project samples. Dr. Zia Bukhari of American Water is the principal contact for American Water for technical issues. Dr. Bukhari has provided technical background and comments on sampling for Cryptosporidium and Giardia, the method 1623 process, infectivity analysis, and genotype analyses of Cryptosporidium and Giardia. William Johnson of American Water is the lead contact for sample receiving, logistics, and American Water laboratory results.

Both BioVir and American Water are being contracted through Weck Laboratories Inc. The contract with Weck is managed through the DWR Bryte Laboratory. Brandon Gee of Weck Laboratories is the primary contact for managing the DWR contract.

Kathleen Harder of the California Central Valley Regional Water Quality Control Board (CVRWCB) has provided background information and water quality data for SRCSD final effluent.

2.3 Specific Quality Assurance Roles

Sid Fong is the Bryte Laboratory QA officer and oversees the implementation of the Bryte Lab QA Plan. Bruce Agee makes available the Bryte Laboratory's Quality Control data. Murage Ngatia is responsible for reviewing this Quality Assurance Project Plan. Dr. Richard Danielson reviews the BioVir lab results to make sure they follow the QA guidelines of the United States Environmental Protection Agency's (EPA). Joe Christen will be responsible for checking the usability of all data and the documentation of data quality for the Pathogen Study.

Comment [m3]: Since Bruce is playing a role, maybe he should be in table 2-1?

Table 2-2 Non-DWR personnel associated with the Project.

Name	Affiliation	Title	Phone	Email
Laura Lazzelle	Stockton	Lab Supervisor	209 937-8786	laura.lazzelle@ci.stockton.ca.us
Mike Sclimenti	MWD	Chemist	909 392-5078	msclimenti@mwdh2o.com
Stuart Krasner	MWD			skrasner@mwdh2o.com
Richard Danielson	BioVir	Microbiologist	707 747-5906	red@biovir.com
Dorian Celio	BioVir	Customer Service	707 747-5906	dmc@biovir.com
Liz Barriga	BioVir	Customer Service	707 747-5906	lb@biovir.com
Zia Bukhari	Am Water	~~Sen~~ Sr. Env Scientist	856 309-4554	zia.bukhari@amwater.com
William Johnson	Am Water	Research Analyst		william.johnson2@amwater.com
Brandon Gee	Weck	Project Manager	626 336-2139	brandon.gee@wecklabs.com
Kathleen Harder	CVRWQB		916 375-6008	kharder@waterboards.ca.gov

3. Project Description

3.1 Work Statement

Data collection will proceed to address the questions "what are the contributions of WWWTP discharges to ambient concentrations of Cryptosporidium and Giardia in Delta waters?" and "what are the WWTP contributions of nitrosamine precursors to Delta waters?" Parameters that can be used as tracers of WWTP effluent in natural waters such as organic nitrogen and personal care products will be collected in addition to the constituents of interest. All field activities will be performed by DWR staff. Laboratory analyses will be performed by the DWR Bryte Laboratory, BioVir, American Water, and the MWD Water Quality Laboratory.

Comment [m4]: These would be most useful in the Objectives section

3.2 Project Schedule

Sampling will be conducted for two years, January 2011 to January 2013. Due to differences in available funding and staff time the sampling frequencies differ between the Pathogen and NDMA studies. Sampling for the Pathogen Study will be conducted every other month. Sampling for the NDMA study will be conducted quarterly, every three months. A write up of the Pathogen Study results and interpretations will be produced after all collected data has been reviewed.

Comment [m5]: Reference Sampling Plan

3.3 Project Parameters Collected

Field measurements will be taken for all samples and will include pH, EC, turbidity, temperature, and dissolved oxygen. Parameters measured by the Bryte Laboratory in support of both studies are listed in Table 3-1.

3.4 Pathogen Study Parameters and Analytical Methods

Parameters collected specific to the Pathogen Study will be counts of and genotyping of Cryptosporidium and Giardia, and Cryptosporidium infectivity (Table 3-2). EPA method 1623 enumeration of Cryptosporidium and Giardia will be performed by BioVir. Genotyping and infectivity assays are research level analyses for which the American Public Health Association ~~does not have~~has not published standard methods. Genotyping is a DNA polymerase chain reaction (PCR) amplification method. The Cryptosporidium infectivity assay is by a cell culture immunofluorescence (IFA) procedure (Bukhari et al 2007).

Comment [m6]: I think you are collecting samples rather than parameters i.e. Samples collected for the Pathogen Study will be for the counts of and genotyping of Cryptosporidium and Giardia, and the infectivity Cryptosporidium ?

3.5 NDMA Study Parameters and Analytical Methods

The MWD Water Quality Lab will be analyzing samples for nitrosamines, NDMA formation potential, and effluent tracers including personal care products, pharmaceuticals, and nutrients (Table 3-3). There are standard methods for quantifying nitrosamines and nutrients in water. To determine concentrations of pharmaceuticals and personal care products MWD will use liquid chromatography tandem mass spectrometry (LC/MS/MS). NDMA formation potential will be determined by gas chromatography mass spectrometry (GC/MS).

Comment [m7]: Are these published std methods?

Table 3-1 Bryte Laboratory parameters collected.

Parameter	Method
Specific Conductivity	Std Method 2510-B
Dissolved Ammonia	EPA 350.1
Total Kjedahl Nitrogen	EPA 351.2
Dissolved Organic Nitrogen	EPA 351.2
Dissolved Nitrate	EPA 300.0
Dissolved Nitrate + Nitrite	Std Method 4500-NO3-F
Alkalinity	Std Method 2340-B
Dissolved Boron	EPA 200.7
Dissolved Chloride	EPA 300.0
Dissolved Sodium	EPA 200.7
Dissolved Potassium	EPA 200.7
Dissolved Sulfate	EPA 300.0
Total Dissolved Solids	Std Method 2540-C
Turbidity	EPA 180.1
pH	EPA 150.1

Table 3-2 Laboratory parameters for pathogen study.

Parameter	Laboratory	Method
Cryptosporidium count	BioVir	EPA 1623
Giardia count	BioVir	EPA 1623
Cryptosporidium recovery	BioVir	EPA 1623
Giardia recovery	BioVir	EPA 1623
Cryptosporidium infectivity*	American Water	cell culture IFA
Cryptosporidium genotype*	American Water	PCR
Giardia genotype*	American Water	PCR

* Analysis performed on the EPA 1623 aliquot.

Table 3-3 MWD Laboratory parameters for the NDMA Study.

Parameter	Method
Dissolved Bromide	EPA 300.0
Dissolved Organic Carbon	EPA 415.1
Dissolved Nitrite	Hach 8507
UVA-254	Std Method 5910-B
Total Ammonia	Std Method 4500 NH3 D
Dissolved Nitrate	EPA 300.0
Nitrosamines	Std Method 6450
Atrazine	LC/MS/MS*
Caffeine	LC/MS/MS
Carbamazepine	LC/MS/MS
Diclofenac	LC/MS/MS
Dilantin	LC/MS/MS
Diuron	LC/MS/MS
Ethinylestradiol	LC/MS/MS
Gemfibrozil	LC/MS/MS
Ibuprofen	LC/MS/MS
Linuron	LC/MS/MS
Primidone	LC/MS/MS
Sucralose	LC/MS/MS
Sulfamethoxazole	LC/MS/MS
Triclosan	LC/MS/MS
tris(2-chloroethyl) phosphate	LC/MS/MS
NDMA formation potential	GC/MS**

* Liquid Chromatography/ tandem Mass Spectrometry

** Gas Chromatography/ Mass Spectrometry

Comment [m8]: Without knowing a whole lot about the substances in question, these seem more like instrumentation rather than standard methods (see comment 7 above)

4. Monitoring Design

Grab samples will be collected every other month by boat from the Sacramento and San Joaquin Rivers upstream and downstream of the WWTP discharge points for the Pathogen Study. While collecting samples the field crew will take field measurement of the parameters listed in Section 3.3. River sampling will be scheduled to occur when flow is proceeding downstream (~~ie~~i.e. ebb tide). Effluent for the Stockton MUD WWTP will be collected at the WWTP in collaboration with personnel of the City of Stockton. When possible Sacramento River water directly adjacent to the downstream side of the SRCSD diffuser pipe will be collected to represent SRCSD WWTP effluent. Sampling for the NDMA Study will be conducted quarterly.

Comment [m9]: This should explain what approach was taken for the design i.e. judgmental, random, or stratified

Comment [m10]: What happens when it is not 'possible'? Since the pathogen study is using unique methods briefly explain those (are these surface samples, depth samples?)

4.1 Sampling Methods

Sampling devi~~s~~ces will be rinsed twice with ambient water prior to sampling. Sampling devices will be decontaminated between stations by rinsing with de-ionized (DI) water. Field Operators will fill out field data sheets immediately after sampling. All sample containers will be labeled with the date, location sampled or unique station ID, parameter to be measured, and sample preparation (filtered/unfiltered). Sampling methods are discussed further in the Project Monitoring Plan.

Comment [m11]: What are these devices? Eventually when a report (especially a journal article) is written, these will have to written in detail.

4.2 Sample Handling and Custody

Sample volume, type of container, and preservation methods are dictated by the analytic method. Table 4-1 lists the sample handling specifications for Project parameters and for pathogen samples. Chain of custody forms will accompany the transfer of samples to the contracted laboratories. Copies of the field data sheets will accompany the transfer of Project samples to Bryte Laboratory.

Table 4-1 Specifications for handling Pathogen Study samples.

Parameter	Method	Sample Prep	Sample Size	Container	Preservative	Hold Time
Specific Conductivity	Std Method 2510-B	unfiltered	500 ml	polyethylene	4˚ C	28 days
Dissolved Ammonia	EPA 350.1	filtered	250 ml	polyethylene	- 20˚ C, dark	28 days
Total Kjedahl Nitrogen	EPA 351.2	unfiltered	250 ml	polyethylene	- 20˚ C, dark	28 days
Dissolved Organic Nitrogen	EPA 351.2	filtered	250 ml	polyethylene	4˚ C	28 days
Dissolved Nitrate	EPA 300.0	filtered	500 ml	polyethylene	4˚ C	28 days
Dissolved Nitrate + Nitrite	Std Method 4500-NO3-F	filtered	250 ml	polyethylene	- 20˚ C, dark	28 days
Alkalinity	Std Method 2320-B	filtered	500 ml	polyethylene	4˚ C	14 days
Dissolved Boron	EPA 200.7	filtered	250 ml	polyethylene	HNO_3, pH<2	6 months
Dissolved Chloride	EPA 300.0	filtered	500 ml	polyethylene	4˚ C	28 days
Dissolved Sodium	EPA 200.7	filtered	250 ml	polyethylene	HNO_3, pH<2	6 months
Dissolved Potassium	EPA 200.7	filtered	250 ml	polyethylene	HNO_3, pH<2	6 months
Dissolved Sulfate	EPA 300.0	filtered	500 ml	polyethylene	4˚ C	28 days
Total Dissolved Solids	Std Method 2540-C	filtered	500 ml	polyethylene	4˚ C	7 days
Turbidity	EPA 180.1	unfiltered	500 ml	polyethylene	4˚ C	48 hours
pH	EPA 150.1	unfiltered	250 ml	polyethylene	4˚ C	*
Cryptosporidium Count	EPA 1623	unfiltered	19 L	polyethylene	1˚ - 10˚ C	96 hours
Giardia Count	EPA 1623	unfiltered	19 L	polyethylene	1˚ - 10˚ C	96 hours

Table adapted from DWR 2006.

** processed as soon as possible*

5. Quality Objectives for Measured Data

Data acquisition activities include field ~~measurements,~~and laboratory measurements. The project data quality objectives for field measurements are listed in Table 5-1. Table 5-2 lists the Bryte Lab quality control limits by method. We have adopted the Bryte quality control limits as the Project data quality objectives for field replicate samples. Table 5-3 lists the data quality objectives for pathogen counts adopted from EPA 1623. Data that does not meet the data quality objectives will be flagged as "not valid" or "estimated" and excluded from formal interpretations of the collected data.

Comment [m12]: Not sure what this means. What field replicates will you be collecting. If you mean field replicates sent blind to the lab, then somewhere there needs to be a description of field dupes sent to the lab as part of the QC measurements

We do not have quality objectives established for the infectivity or genotype results. For the infectivity analysis American Water has a positive and negative control for each batch. The positive control consists of inoculating a subsample of the cell culture with a known number of infectious *Cryptosporidium parvum* oocysts, incubating the inoculated culture, and then performing IFA enumeration to calculate the number of infectious oocysts. The positive control demonstrates the cultures susceptibility to infection and the accuracy of IFA method. The negative control consists of performing the IFA method on a cell culture that has been inoculated with a blank. The negative control demonstrates the resistance of the method to false positives.

5.1 Data Quality Indicators

5.1.1 Accuracy

Accuracy is a measure of how close a measured value is to the known value. Tests of the field instrument's accuracy are specific to the instrument and are conducted by Field Unit staff. Instruments of satisfactory accuracy will be used whenever possible. If an instrument of unsatisfactory accuracy is used all measurements from that instrument will be flagged as "not valid" or "estimated". Our objectives for field instrument accuracy are presented in Table 5-1. Field instruments are calibrated and checked against standards to assure their accuracy. The pH probe is calibrated prior to each field trip to three standard buffer solutions of; pH 4.0, pH 7.0, and pH 10 and is checked against a 7.0 pH buffer prior to and after the field run. Turbidimeters are calibrated once every three months and are checked against a 20 ntu standard after each day of use. Electrical conductivity probes are calibrated to a 718 µS/cm standard and checked against the standard before and after each field run.

Comment [m13]: Note: True value is only known for certified standards. However, if the instrument is within certified limits when tested, we can reasonably assume that the field measurements are of acceptable quality, i.e. valid, but cannot qualify them as true values.

The accuracy of Bryte Chemical Laboratory analyses are assessed by running check standards, laboratory control samples, and matrix spikes of environmental samples (DWR 2006).

The accuracy of pathogen counts will be assessed by matrix spikes recoveries; counts of environmental samples spiked with known counts of pathogens. Matrix spikes will be conducted no less than quarterly (every 3 months) for the Sacramento and San Joaquin River samples. We have adopted EPA's method 1623 performance criteria for mean pathogen recoveries by species as our accuracy objectives. Mean recoveries will be calculated for each matrix. The three operative matrices for this Project are Sacramento River, San Joaquin River, and Stockton WWTP effluent. If the percent recovery for an individual matrix spike falls outside the objective range for the mean recovery then the count data for the corresponding environmental sample will be flagged as "estimated". If the mean recovery for a matrix is below the acceptance criteria then all samples that correspond to the matrix will be flagged as "estimated".

5.1.2 Precision

Precision is a measure of how numerically close replicate measures are to each other. Precision will be reported as relative percent difference (RPD) or relative standard deviation (RSD). Bryte Laboratory's QA program has control limits for precision that must be met in order to report analytical results.

Pathogen count precision will be assessed by calculating the relative standard deviation of matrix spikes.

Table 5-1 Data quality objectives for field measurements.

Parameter	Unit	Resolution	Accuracy	Precision
Dissolved Oxygen	mg/L	0.1	± 10%	-
pH	pH units	0.1	-	-
Specific Conductivity	µS/cm	1	± 10%	-
Temperature	˚C	0.1	-	-
Turbidity	NTU	0.1	± 10%	-

5.2 Representativeness

Field personnel will conduct sampling and measurements in such a manner as to ensure that they are representative of the water bodies being studied. Specifically field personnel will follow the procedures of the MWQI field manual (DWR 1995). Duplicate samples from one field location will be submitted each field run to assess the reproducibility of results. Environmental samples for pathogen enumeration will be collected as a composite sample of a near surface transect of the waterway using equipment and methods that follow EPA method 1623 guidelines for sample collection.

Comment [m14]: Field personnel cannot ensure representativeness. Representativeness can only be assured in the design phase by selecting stations, sampling frequency, correct number of samples that can capture the environmental conditions. The field personnel can only follow what is in the sampling plan.

Table 5-2 Bryte Laboratory quality control limits.

Parameter	Method	Units	Rpt Limit	Sample MS* % Recovery	Sample MS* RPD	Lab Control Standards & MS* % Recovery	Lab Control Standards & MS* RPD
Specific Conductivity	Std Method 2510-B	µS/cm	1	-	≤ 20	-	≤ 20
Ammonia	EPA 350.1	mg/L N	0.01	86 - 118	≤ 20	-	-
Total Kjedahl Nitrogen	EPA 351.2	mg/L N	0.1	74 - 127	≤ 30	70 - 130	≤ 30
Dissolved Organic Nitrogen	EPA 351.2	mg/L N	0.1	74 - 127	≤ 30	70 - 130	≤ 30
Dissolved Nitrate	EPA 300.0	mg/L	0.1	79 - 119	≤ 20	80 - 120	≤ 20
Dissolved Nitrate + Nitrite	Std Method 4500-NO3-F	mg/L N	0.01	79 - 119	≤ 20	80 - 120	≤ 20
Alkalinity	Std Method 2320-B	mg/L $CaCO_3$	1	78 - 116	≤ 20	85 - 125	≤ 20
Dissolved Boron	EPA 200.7	mg/L	0.1	79 - 112	≤ 20	85 - 125	≤ 20
Dissolved Chloride	EPA 300.0	mg/L	1	89 - 116	≤ 20	85 - 125	≤ 20
Dissolved Sodium	EPA 200.7	mg/L	1	82 - 116	≤ 20	85 - 125	≤ 20
Dissolved Potassium	EPA 200.7	mg/L	0.5	82 - 108	≤ 20	85 - 125	≤ 20
Dissolved Sulfate	EPA 300.0	mg/L	1	82 - 120	≤ 20	85 - 125	≤ 20
Total Dissolved Solids	Std Method 2540-C	mg/L	1	-	≤ 20	85 - 125	≤ 20
Turbidity	EPA 180.1	ntu	1	-	≤ 20	85 - 125	≤ 20
pH	EPA 150.1	pH unit	0.1	-	≤ 20	85 - 125	≤ 20

Table adapted from DWR 2006.

** MS – matrix spike*

Comment [m15]: Update to 2010 version

Table 5-3 Performance criteria for EPA method 1623.

Parameter	Sample Type	Units	Reporting Limit	Mean % Recovery	RSD
Cryptosporidium Count	Matrix Spike	#/L	-	13 - 111	≤ 55
Giardia Count	Matrix Spike	#/L	-	15 - 118	≤ 49
Cryptosporidium Count	OPR Spike	#/L	-	11 - 100	-
Giardia Count	OPR Spike	#/L	-	14 - 100	-

Table adapted from EPA 2005.

6. Quality Control

Comment [m16]: What about field duplicates?

Sample integrity will be ensured by following sampling procedures that maintain sampling and filtering equipment free of contamination. Field blanks and filter blanks will be submitted for laboratory analyses to test for contamination. If there is evidence of contamination present all the corresponding data will be flagged appropriately and actions will be taken to identify and remove future sources of contamination.

The Bryte Laboratory QA program requires that laboratory accuracy and precision be assessed for every sample batch. The laboratory quality control criteria are listed in Table 5-2. If a check on a laboratory analytical method falls outside of the control limits then Bryte Laboratory staff will take measures to identify and correct the performance (DWR 2006). The results of laboratory checks that pertain to this project will be communicated to the Principal Investigator.

Comment [m17]: There is a 2010 version

BioVir is in compliance with the quality check criteria of EPA method 1623 (Rick Danielson pers comm) which entails an ongoing analysis of precision and recovery (OPR) and a method blank. An OPR sample is a spike of reagent water with a known number of organisms. The OPR must be run once a week or once every 20 samples if more than 20 are processed in a week (EPA 2005). The method blank is a performance of the method on reagent water. The control limits for OPR samples are listed in Table 5-3. BioVir has agreed to provide the results of their ongoing precision and recovery analysis for Method 1623 to the Principal Investigator.

7. Instrument/Equipment Testing, Inspection, and Maintenance

Field sampling equipment is rinsed with distilled water after a sample collection. Sample collection gear is scrubbed and rinsed with distilled water after a sample run. Field instruments are maintained by the Field Unit. The Field Unit replaces some instrument parts (DO membranes, pH probes..) routinely and as needed. The Field Unit tests sensors against standards and records results on a routine schedule. The pH instrument and DO sensor are calibrated prior to every field trip. The turbidimeters are checked against distilled water prior to every field trip and the results recorded. EC probes are checked against a standard prior to every field trip.

Bryte Laboratory staff performs routine maintenance on analytical instruments as ~~the~~ per manufacturer's recommendations (DWR 2006). Equipment log books are maintained and instrument performance is verified after any maintenance is performed.

8. Data Management

The principal investigator will maintain an MS Access database that contains all measurement data, data documentation, and quality check data for this study. Data will be entered into appropriate tables in the database. Field equipment will be logged into an INSTRUMENTS table. Field activities and measurements will be recorded into Field Data Sheets. Each field instrument has a unique identifier. Data captured by the Field Data Sheets will be entered into a FIELD-RESULTS table. Laboratory results including duplicates will be entered into a LAB-RESULTS table. Results for pathogen matrix spikes will be entered into a MATRIX-SPIKE table. Each measurement will have a data qualifier/flag.

9. Data Review

Specifications for sampling, handling, field measurements, and laboratory analyses are described in previous sections of this QAPP (4,5,7). These specifications are criteria that must be met for the acceptance of analytical runs and field measurements. Each batch of results will be checked against these criteria. The outcomes of quality checks for data quality indicators (accuracy, precision) will be compared to the measurement quality objectives of section 5. Monitoring data results will be classified according to Table 9-1.

Table 9-1 Result Qualifiers/Flags for Project Data.

Qualifier	Definition
unknown	information for review is not available.
not checked	data quality has not been reviewed.
not valid	result came from a malfunctioning instrument or analytical test performing unacceptably.
estimated	not valid but professional judgment is that the result can be used with caution.
valid	measurement system met performance criteria and data quality objectives.

10. Verification and Validation Methods

Data verification and validation will consists of the following phases –

- Inventory - lists sites, station visits, samples, number of quality checks
- QAPP comparison - compare conducted activities to procedures in QAPP
- Data Entry – Enter data into database or spreadsheets.
- Matching – Align results to their corresponding QC datum.
- Correctness – Spot checks or line by line editing of entered data.
- Sample Validation – Summarize check's outcomes, review field notes.
- Error Calculation – Calculate accuracy and precision.
- Assess Performance – Compare errors to quality control criteria.

11. Documents and Records

All records generated by the Pathogen Study and received from participating laboratories, including field data sheets and chain of custody forms, will be stored at the MWQI office in West Sacramento. Electronic datasets and electronic copies of field records will be maintained by Joe Christen and a copy shall be stored on the MWQI network shared drive. A backup copy of all electronic files will be stored on CD.

Comment [m18]: What about NDMA data?

12. References

Bukhari, Zia, David Holt, Michael W. Ware, and Frank W. Scaefer III. 2007. Blind trials evaluating in vitro infectivity of *Cryptosporidium* oocysts using cell culture immunofluorescence. Canadian Journal of Microbiology 35: 656-663.

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EPA. 2005. Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA. United States Environmental Protection Agency.

Comment [m19]: This is no longer available at this website. The new one is 2010